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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,265	04/15/2004	Joseph C. Dinardo	20801/1204513-US1	8306
7278	7590	07/10/2007	EXAMINER	
DARBY & DARBY P.C.			YU, GINA C	
P.O. BOX 770			ART UNIT	
Church Street Station			PAPER NUMBER	
New York, NY 10008-0770			1617	
			MAIL DATE	DELIVERY MODE
			07/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/825,265

Applicant(s)

DINARDO ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 04-15-04, 11-15-04, 01-10-05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Neudecker et al. (WO 01/03657).**

Neudecker teaches that idebenone, a derivative of idebenone, or a combination thereof, is used in a topical skin preparation for prophylaxis and/or treatment of a skin change, wherein the skin change includes photodamage of the skin by UV light and inflammation. See col. 5, line 53 – col. 6, line 20. Thus the claimed methods of instant claims 1-3, 11, 14-19, 21, 27, and 38 are anticipated.

The reference discloses a cosmetic O/W cream composition comprising 0.5 % idebenone, titanium dioxide, and sodium lactate. See Example 2; instant claims 45-48, and 50. Example 3 is a cream comprising 1 % of idebenone sulphonate, 0.5 % of idebenone, and retinoid. See instant claims 51-56. For claims 1 and 27, since the prior art cosmetic composition of Example 3 contains the same component as required by the instant claim, the claimed method is inherently practiced every time the prior art is used. See instant claims 1, 13, and 27-37. Whether the preparation is an over-the-counter product is also an intended future use. See instant claim 20.

Example 8 teaches a sunscreen emulsion comprising 0.50% of idebenone, vitamin E, and octylmethoxy cinnamate. The method of using the composition for the purpose of the instant claims, claims 1, and 39, are inherently practiced every time the prior art composition is used. See instant claims 1, 2, 4-7, 9-12, 15-25. A hydrophilic idebenone ester is disclosed on col. 5, lines 39 – 64. See instant claims 26, 38, 49, and 56.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 1-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 6756045 B1.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of using topical compositions comprising idebenone and/or its derivatives and same auxiliaries to protect and treat skin from damages caused by UV light.

**Claims 1-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-55 of copending Application No. 10/822,074.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of using topical compositions comprising idebenone and/or its derivatives and same auxiliaries to protect and treat skin from damages caused by UV light. See claim 29 of the '074 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 1-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 11/057364.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of using topical compositions comprising idebenone and/or its derivatives and same auxiliaries to protect and treat skin from damages caused by UV light. See claim 29 of the '074 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 1-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 11/057364.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of using topical compositions comprising idebenone and/or its derivatives and same auxiliaries to protect and treat skin from damages caused by UV light. See claim 13 of the '364 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 1-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 11/010854.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of using topical compositions comprising idebenone and/or its derivatives and same auxiliaries to protect and treat skin from damages caused by UV light. See claim 10 of the '854 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gina C. Yu  
Patent Examiner